UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

DALLAS SWANK, et al.,

Plaintiffs,

v.

DEPUY SYNTHES SALES INC., et al.,

Defendants.

CASE NO. C20-1373-LK

ORDER GRANTING IN-PART AND DENYING IN-PART PLAINTIFFS' MOTION TO COMPEL DISCOVERY

Defendants (collectively, "DePuy") manufactured the DePuy Agility Ankles, which were surgically implanted in plaintiff Dallas Swank's lower extremities. Dkt. 1-2. Plaintiffs allege that the DePuy Agility Ankles were not safe and contributed to Mr. Swank's subsequent injuries. *Id.* Plaintiffs move to compel DuPuy to produce six categories of items. Dkt. 23. DePuy opposes the plaintiffs' motion to compel as overbroad and as seeking irrelevant information given the DePuy Agility Ankles at-issue were inserted in 2003, were no longer in use after 2006, and are different from the DePuy **LP** Agility Ankles subject to a 2011 FDA Warning Letter.

There is no dispute that discovery should be limited to "the type of Agility Total Ankle Prosthesis that is the subject of this case." Dkt. 23-2, at 15. The Court acknowledges DuPuy's reasonable concerns regarding the possible overbreadth of some of plaintiffs' requests for information about later-developed products. Nonetheless, plaintiff has presented material

suggesting that more than one version of DuPuy Agility Ankles may be involved in this case: Mr. Swank received a replacement of a DePuy Agility Ankle in 2008, i.e., after the time that the original version was purportedly no longer in use, *see* Dkt. 26, at 2; Dkt. 26-2, at 9; and the 2011 FDA Warning Letter refers both to other versions of ankle devices and to DuPuy "utilizing existing lines of products that have FDA clearance or approval to manufacture the[] devices [under investigation]," Dkt. 23-2, at 5, 7. The Court therefore **GRANTS in-part and DENIES in-part** plaintiffs' motion to compel as follows.

1. **The FDA Warning Letter issued March 15, 2002 together with the responses and follow-up by DePuy and the FDA.**

The Court denies plaintiffs' motion to compel production of the March 2002 Warning Letter and responses because DePuy has already informed plaintiffs of the inability to locate or provide this documentation. Dkt. 23-2, at 38; Dkt. 24, at 4.

2. **The December 8, 2011 FDA Warning Letter with the responses and follow-up by DePuy and the FDA.**

It is unnecessary for DePuy to produce the December 2011 FDA Warning Letter because it is publicly available and was submitted by plaintiffs in support of their motion to compel. *See* Dkt. 23-2. The Court grants plaintiffs' request for the responses and follow-up by DePuy and the FDA to the December 2011 Warning Letter because (a) DePuy avers that in 2006 it ceased offering the Agility Ankle that Mr. Swank received in 2003, Dkt. 24, at 5; (b) DePuy avers that it received 510(k) clearance for the Agility LP Total Ankle Prosthesis in 2006; (c) a medical record shows that Mr. Swank received a replacement of some version of the Agility Ankle in 2008, Dkt. 26-2, at 9; (d) it is plausible that Mr. Swank received a form of the Agility LP Ankle (or other DuPuy ankle device) in 2008 given his original version was no longer in use as of 2006; and (e)

the 2011 FDA Warning Letter refers both to the "Agility LP Total Ankle Prosthesis" as well as to other ankle replacement devices, including those that had received prior FDA approval, Dkt. 23-2, at 5, 7.

3. Copies of FDA Form 483 (notices of observations) related to DePuy.

The Court grants plaintiffs' motion to compel production of copies of FDA Form 483 related to DePuy to the extent that the documents plausibly relate to the type of Agility Total Ankle Prosthesis that is the subject of this case, i.e., versions of the Agility Ankle that were in use during Mr. Swank's procedures in 2003 and 2008.

4. Copies of FDA inspections and reports related to DePuy.

The Court grants plaintiffs' motion to compel production of copies of FDA inspections and reports related to DePuy to the extent that the documents plausibly relate to the type of Agility Total Ankle Prosthesis that is the subject of this case, i.e., versions of the Agility Ankle that were in use during Mr. Swank's procedures in 2003 and 2008.

5. Copies of FDA Forms 482 (notices of inspection) related to DePuy.

The Court grants plaintiffs' motion to compel production of copies of FDA Forms 482 related to DePuy to the extent that the documents plausibly relate to the type of Agility Total Ankle Prosthesis that is the subject of this case, i.e., versions of the Agility Ankle that were in use during Mr. Swank's procedures in 2003 and 2008.

6. Copies of the 510(k) submissions related to Agility Ankles.

The Court grants plaintiffs' motion to compel production of copies of the 510(k) submissions to the extent that the documents plausibly relate to the type of Agility Total Ankle Prosthesis that is the subject of this case, i.e., versions of the Agility Ankle that were in use during Mr. Swank's procedures in 2003 and 2008.

DATED this 14th day of March, 2022.

BRIAN A. TSUCHIDA
United States Magistrate Judge